



CERTIFIED MAIL - RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

January 21, 1998

WARNING LETTER

Ms. Cindy H. Chon, Owner
Therapeutic Home Care
318 South A Street
Oxnard, CA 93030

WL-14-8

Dear Ms. Chon:

During an inspection of your facility, conducted on December 3 to December 5 and 11, 1997, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211). These deviations cause your liquid oxygen products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The deviations are as follows:

1. Failure to assure that liquid oxygen conforms to the requirements for identity and strength, in that employees are not trained to witness testing done by the supplier, the supplier's analysis is not periodically verified, and your firm's oxygen analyzer, the [REDACTED] Oxygen Analyzer, which is used for identity testing, is not calibrated against an appropriate standard.
2. Failure to establish complete written procedures for production and process controls covering all aspects of your firm's operations. There is no documentation which reflects that the written standard operating procedures you currently have were reviewed and approved by a responsible individual.
3. Failure to establish adequate batch production and control records for each batch of liquid oxygen transfilled, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, in that the Batch Quality Control/Transfilling Log referred to in the written procedures, is not used.
4. Failure to assure personnel have education and training to perform their assigned functions, in that there are no records to indicate that personnel are trained to witness testing of the Liquid Oxygen, U.S.P. and there are no written procedures for training employees in current good manufacturing practices, cleaning and maintenance of equipment and handling of complaints.

The above does not represent an all inclusive listing of the deficiencies noted during the inspection of your firm. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations and to assure that your products are correctly labeled. Federal agencies are advised of the issuance of all warning letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

We have enclosed the latest copy of a speech by our National Expert, Mr. Duane Sylvia, entitled "Fresh Air '97' - A Look At FDA's Medical Gas Requirements". This speech will assist you in understanding your responsibilities as a medical gas manufacturer. Pages 4-6 specifically cover testing of incoming liquid oxygen and cryogenic-home vessels.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your written response should be addressed to:

Mary M. LoVetere
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,


Elaine C. Messa
District Director

Enclosure

Page 3
WL-14-8

cc: State Department of Public Health
Environmental Health Services
Chief, Food and Drug Branch
714 "P" Street, Room 440
Sacramento, CA 95814